Remarks

This communication is responsive to the final Office action mailed April 30, 2008. Claim 4 has been amended to correct a typographical error. Claim 30 has been amended to depend from claim 20, and the term "instilling" has been amended to "injecting" to provide antecedent basis to claim 20. No new matter has been added. Reconsideration of the application in view of the remarks presented below is respectfully requested.

Claim Rejections - 35 U.S.C. § 102

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al. (U.S. Pat No. 5,632,984; "Wong '984").

Applicants respectfully traverse the rejection of claim 1 under 35 U.S.C. 102(b).

Wong '984 relates to the introduction of a drug into the posterior segment of the eye. Introduction into the posterior segment allows diffusion of the drug throughout the vitreous within the posterior segment and further into the entire retina, the choroids and opposed sclera. According to Wong '984 the drug is directly available at the macula, the site where the drug is needed, and will be maintained at the effective dosage (see, col. 4, lines 1-9).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131. The identical invention must be shown in as complete detail as is contained in the claim. MPEP 2131 citing Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989).

With respect to claim 1, Wong '984 fails to describe, either expressly or inherently, a method for administering a therapeutic medium to a posterior segment of an eye comprising instilling a therapeutic medium sub-retinally; wherein the step of instilling comprises injecting a solution including the therapeutic medium in the sub-retinal space. Rather, Wong '984 is concerned with the introduction of a drug into the posterior segment of the eye into the vitreous. Since Wong '984 does not teach or suggest instilling a therapeutic medium sub-retinally, Wong '984 does not anticipate claim 1. In

view of the foregoing, the rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Wong '984 is improper and should be withdrawn.

Claim Rejections - 35 U.S.C. §103

Claims 1-4, 6, 7, 8, 11, 20, 27, 58-61, 63 and 64 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (U.S. Pat No. 5,869,079; "Wong '079") in view of Wong et al. (U.S. Pat No. 5,632,984; Wong '984).

Applicants respectfully traverse the rejection of claims 1-4, 6, 7, 8, 11, 20, 27, 58-61, 63 and 64 stand rejected under 35 U.S.C. 103(a).

Wong '079 relates to compositions and methods for biodegradable implants that are formulated to provide a controlled, sustained drug release. The release rate is modulated by combining in the implant hydrophobic and hydrophilic agents. The release modulator may act to accelerate or retard the rate of release. Wong et al. teaches that suitable sites include the anterior chamber, posterior chamber, vitreous cavity, suprachoroidal space, subconjunctivea, episcleral, intracorneal, epicorneal and sclera.

Wong '984 relates to the introduction of a drug into the posterior segment of the eye. Introduction into the posterior segment allows diffusion of the drug throughout the vitreous within the posterior segment and further into the entire retina, the choroids and opposed sclera. According to Wong '984 the drug is directly available at the macula, the site where the drug is needed, and will be maintained at an effective dosage (see, col. 4, lines 1-9).

With respect to claims 1 and 20, Wong '079 is concerned with the implantation of solid biodegradable implants. Wong '079 does not teach or suggest the instilling a therapeutic medium sub-retinally; wherein the step of instilling comprises injecting a solution including the therapeutic medium in the sub-retinal space. Rather, Wong '079 teaches that the solid implant includes a combination of hydrophilic and hydrophobic entities in order to provide a controlled, sustained drug release for an extended period. The rate of release of the therapeutically active agent is controlled by the rate of transport through the polymeric matrix and the action of the modulator. Wong '079 also teaches that the size and form of the implant can be used to control the rate of release, period of

treatment, and drug concentration at the site of implantation. Contrary to the position taken in the Office Action, there is no motivation for one of skill in the art to modify Wong '079 using the teachings of Wong '984 because to do so would be in direct contradiction to the teachings of Wong '079, including the advantages of utilizing a solid implant comprising a hydrophilic and hydrophobic entity to control elution rate; and the further ability to control the elution rate of release, period of treatment, and drug concentration by varying the size and form of the implant.

Pending claim 58 relates to a method for administering a therapeutic medium to a posterior segment of an eye. The method comprises the step of: implanting a sustained release delivery device in a sub-retinal space; wherein said sustained release delivery device comprises: (a) a core comprising a biocompatible matrix and the therapeutic medium; and (b) a jacket surrounding the core comprising a biocompatible membrane comprising a polymer selected from polyacrylates, polyvinylidenes, polyvinyl chloride copolymers, polyurethanes, polystyrenes, polyamides, cellulose acetates, cellulose nitrates, polysulfones, polyphosphazenes, polyacrylonitriles, poly(acrylonitile/covinyl chloride), derivatives, copolymers, and mixtures thereof.

Neither Wong '079, or Wong '984 teach or suggest a method of treating an eye comprising implanting a sustained release delivery device comprising a core comprising a biocompatible polymer and a therapeutic medium; and a jacket surrounding said core comprising a biocompatible membrane comprising a polymer selected from polyacrylates, polyvinylidenes, polyvinyl chloride copolymers, polyurethanes, polystyrenes, polyamides, cellulose acetates, cellulose nitrates, polysulfones, polyphosphazenes, polyacrylonitriles, poly(acrylonitile/covinyl chloride), derivatives, copolymers, and mixtures thereof. The surrounding jacket allows the elution rate of the therapeutic medium to be controlled, for example, by selection of the polymer type and/or thickness.

With respect to claims 58-64, the Office Action admits that "Wong et al. does not specifically teach the polymers polyacrylates, polyvinylidenes, polyvinyl chloride copolymers, polyurethanes, polystyrenes, polyamides, cellulose acetates, cellulose nitrates, polysulfones, polyphosphazenes, polyacrylonitriles, poly(acrylonitile/covinyl

chloride), derivatives, copolymers, and mixtures thereof." However, the Office Action goes on to conclude that ... "To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Wong et al. and the specific polymers disclosed in claim 58 because of the following teachings of Wong et al.: 1) the selection of the polymeric composition employed will vary with the site of administration, the desired period of treatment, patient tolerance, the nature of the disease to be treated and the like (see column 5, lines 27-33); 2) characteristics of the polymers will include biodegradability at the site of implantation, compatibility with the agent of interest, ease of encapsulation and the half-life in the physiological environment (see column 5, lines 27-33); and 3) biodegradable polymeric compositions may be organic esters, ethers, anhydrides, amides, orthoestersor the like (see column 5, lines 38-53)."

Applicant does not agree with the position taken in the Office Action. Neither Wong '079 or Wong '984 teach or suggest the use of an implant having the structure as set forth in claim 58 including a core comprising a biocompatible polymer and a therapeutic medium; and a jacket surrounding said core comprising a biocompatible membrane comprising a polymer selected from polyacrylates, polyvinylidenes, polyvinyl chloride copolymers, polyurethanes, polystyrenes, polyamides, cellulose acetates, cellulose nitrates, polysulfones, polyphosphazenes, polyacrylonitriles, poly(acrylonitile/covinyl chloride), derivatives, copolymers, and mixtures thereof. In addition, the general guidelines provided in Wong '079 for desirable characteristics would in no way teach or suggest the use of Applicant's claimed polymers in the form of a jacket surrounding a biocompatible core.

In view of the foregoing, it is submitted that the rejection over Wong '079 in view of Wong '984 has been overcome and should be withdrawn.

Claims 5, 19 and 62 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (U.S. Pat No. 5,869,079), in view of Wong et al. (U.S. Pat No. 5,632,984; Wong'984) as applied to claims 1-4, 6, 7, 8, 11, 20, 27, 58-61, 63 and 64 above in view of Hughes et al. (U.S. Pat No. 5,962,027; "Hughes '027").

Applicants respectfully traverse the rejection of claims 5, 19, and 62 under 35 U.S.C. 103(a).

Claim 19 was previously cancelled (see, Response of January 28, 2008).

Claims 5 and 62 are dependent claims which include all of the limitations of the independent claims from which they depend. The independent claims are patentable for the reasons set forth herein. Therefore, these dependent claims are patentable for at least the same reasons as presented for the independent claims.

Claims 1, 8 and 11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Louis (U.S. Patent No. 5,641,750) in view of Wong et al. (U.S. Patent. No. 5,869,079) and further view of Hughes et al. (U.S. Patent No. 5,962,027).

Applicants respectfully traverse the rejection of claims 1, 8, and 11 under 35 U.S.C. 103(a).

Louis relates to a method for treating vision loss due to photoreceptor degeneration by administering a therapeutically effective amount of glial cell line-derived neurotrophic factor (GDNF) protein product. According to one aspect of the invention, methods are provided for treating vision loss due to photoreceptor degeneration by administering a therapeutically effective amount of GDNF protein product. It is contemplated that such GDNF protein products would include a GDNF protein such as that depicted by the amino acid sequence set forth in SEQ ID NO:1, as well as variants and derivatives thereof. It is reported that administration of GDNF protein product promotes the survival and regeneration of damaged photoreceptor neurons, which are the main population of neurons damaged in retinal degenerations leading to blindness.

According to Louis, GDNF protein product may be administered intraocularly at a dose between about 0.001 mg/day and 10 mg/day, preferably at a dose between about 0.01 mg/day and 1 mg/day, and most preferably at a dose between about 0.1 mg/day and

0.5 mg/day. It is reported that the delivery means for the administration of a GDNF protein product in the treatment of ophthalmic conditions or diseases may advantageously involve topical formulations, ocular inserts, ocular injection, ocular implants, cell therapy or gene therapy.

As admitted in the Office Action, Louis does not teach administration to the posterior segment of the eye by instilling a therapeutic medium sub-retinally. The Office Action relies upon Wong '079 and Hughes to cure the deficiency in Louis.

As discussed hereinabove, Wong '079 relates to compositions and methods for biodegradable implants that are formulated to provide a controlled, sustained drug release. The release rate is modulated by combining in the implant hydrophobic and hydrophilic agents. Wong '079 does not teach or suggest injecting a solution including a therapeutic medium in the sub-retinal space.

Hughes relates to a method for the preparation of a graft for transplantation into the subretinal area of a host eye. As with Wong et al., Hughes does not teach or suggest injecting a solution including a therapeutic medium into the sub-retinal space.

There is no motivation to combine the teachings of Louis with Wong et al. or Hughes. Louis explicitly reports that the delivery means include topical formulations, ocular inserts, ocular injection, ocular implants, cell therapy or gene therapy. There is no reason to modify the delivery means that are specifically taught in Louis using the teaching of Wong et al. and/or Hughes which relate to solid implants and grafts, respectively.

In view of the foregoing, it is submitted that the rejection over Louis in view of Wong et al. and further view of Hughes has been overcome and should be withdrawn.

Conclusion

It is respectfully submitted that the claims and the present application are now in condition for allowance. Approval of the application and allowance of the claims is earnestly solicited. In the event that a phone conference between the Examiner and the undersigned would help resolve any remaining issues in the application, the Examiner is invited to contact undersigned at (651) 275-9830.

Respectfully Submitted,

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By: _____

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